EXHIBIT C

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
PATRICIA LINDBERG and CARL LINDBERG **Plaintiffs** **v.** **ETHICON, INC., et al** **Defendants**	**Case No. 2:12-MD-01311**

RULE 26 EXPERT REPORT OF KONSTANTIN WALMSLEY, MD

My name is Konstantin Walmsley. I have been retained by Bern Ripka LLP to give medical opinions related to Patricia Lindberg. I am being compensated at the rate of $500 dollars/hour. My curriculum vitae and schedule of previous testimony are attached to this report. All opinions set forth in this report are based upon my personal knowledge, as well as my review of the pertinent medical records, my education, training, skill, experience as a physician, and review of the pertinent medical literature. All of my opinions are based upon a reasonable degree of medical probability.

I am a licensed physician in the State of New Jersey and a board certified urologist. I am familiar with the evaluation and treatment of stress urinary incontinence. I have implanted transvaginal mesh and am familiar with the properties of these devices and proper implantation technique for these devices.

I am familiar with the evaluation and treatment of stress urinary incontinence. I have implanted transvaginal mesh, including mid urethral slings, and am familiar with the properties of these devices and proper implantation technique for these devices. Further, I am familiar with non-mesh options for the treatment of stress urinary incontinence including autologous tissue based slings, biological graft-based slings, and periurethral bulking procedures. I have attended

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training provided by Ethicon, Inc. including training on TVT devices. Additionally, I have explanted and performed other revision procedures on transobturator and retropubic mid-urethral slings including the TVT device.

Additionally, in light of my training, knowledge, experience and qualifications as set forth above and in the attached C.V., I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh implants.

The most common complications are pelvic pain, scarring in the vagina and pelvic floor, pain into the legs and thighs, dyspareunia, chronic inflammation of tissue, scar bands or scar plates in the vagina, vaginal shortening or stenosis, erosion, exposure or protrusion of mesh into and through tissues or organs, voiding dysfunction relating to pelvic floor scarring (de novo urinary urgency, urge incontinence, and incomplete emptying), and nerve entrapment. In diagnosing and treating patients with mesh related complications, I often determine the cause of the patients complications based upon an interview with the patient, a review of her medical records, and knowledge of her prior medical history.

I have reviewed the following medical records and depositions with accompanying exhibits pertaining to Patricia Lindberg. Although a case-specific expert report will be submitted in future, I will be providing general expert opinions regarding Patricia Lindberg forthwith.

- Complaint (filed in West Virginia)
- Amended Short Form Complaint
- Plaintiff Fact Sheet
- Medical Records, Affiliated Urology Specialists, LTD
- Medical Records, Methodist Medical Center
- Medical Records, Boyd Obstetrics and Gynecology
- Deposition, Carl Lindberg
- Deposition, Patricia Lindberg

In addition to the review of the medical records and depositions listed above, I have also reviewed the following medical literature and other TVM related documents and have relied, in part, on the documents below in addition to my medical and clinical experience in forming my opinions:

- AMA 8.08
- TVT Instructions for Use
- C.G. Nilsson et al "Seventeen years' follow-up of the tension free vaginal tape procedure for female stress urinary incontinence." Int. Urogynecol. J. (2013) 24:1265-69

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- P. Hilton "A clinical and urodynamic study comparing the Stamey bladder neck suspension and suburethral sling procedures in treatment of genuine stress incontinence" British Journal of Obst. & Gynecol (February 1989, Vol 96, pp. 213-220
- H. Enzelsberger et. al "Comparison of Burch and Lyodura Sling Procedures for Repair of Unsucessful Incontinence Surgery" Obstet & Gynecol, Vol 88, No. 2, August 1996
- A.S. Arunkalaivanan et al "Randomized trial of porcine dermal sling (Pelvicol implant) vs. Tension-free Vaginal Tape (TVT) in the Surgical treatment of stress incontinence: a questionnaire based study" Int. Urogynecol J (2003), 14: 17-23
- K. Guerrero et al "A randomized controlled trial comparing two autologous fascial sling techniques for the treatment of stress urinary incontinence in women: short, medium and long-term follow-up" Int. Urogynecol J (2007) 18:1263-1270
- B. Welk et al, "Removal or Revision of Vaginal Mesh Used for the Treatment of Stress Urinary Incontience" JAMA Surgery, Published Online September 9, 2015.
- E. Petri et al., "Complications of synthetic slings used in female stress urinary incontinence and applicability of the new IUGA-ICS classification" Eur. J. of Obstet. & Gynecol. and Reprod. Bio. 165 (2010) 347-351
- B. Klosterhalfen et al., "Functional and morphological evaluation of different polypropylene-mesh modifications for abdominal wall repair" Biomaterials (1998) 2235-46
- J. Anger et al., "Complications of Sling Surgery Among Female Medical Beneficiaries" Obstet. & Gynecol. Vol. 109, No. 3 (March 2007)
- P. Moalli et al, "Tensile Properties of five commonly used mid-urethral sling relative to the TVT" Int. Urogynecol J (2008) 19:655-663
- A. Clave et al, "Polypropylene as a reinfomrcement in pelvic surgery is not inert: comparative analysis of 100 explants" Int. Urogynecol J (2010) 21:261-270
- O. Chinthakanan et al., "Mesh Removal Following Sling/Mesh Placement: A Multicenter Study" Int. Urogynecol. J (2014) 25 (Suppl 1) S-139-40

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- O. Chinthakanan et al, "Indication and Surgical Treatment of MidUrethral Sling Complications: A Multicenter Study" Int. Urogynecol. J (2014) 25 (Suppl 1) S-142-43
- E. Petri et al., "Comparison of late complications in retropubic and transobturator slings in stress urinary incontinence" Int. Urogynecol. J. (2012) 23:321-325
- S. Abbott et al., "Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study" American J. of Obset. & Gynecol (February 2014) 163.e1-8.
- G. Agnew et al, "Functional outcomes following surgical management of pain, exposure or extrusion following a suburethral tape insertion for urinary stress incontinence" Int. Urogynecol J. (2014) 25:235-239
- J. Duckett et al, "Pain after suburethral sling insertion for urinary stress incontinence" Int. Urogynecol J. (2013) 24:195-201
- C. Skala et al., "The IUGA/ICS classification of complications of prosthesis and graft insertion" Int. Urogynecol J (2011) 22:1429-1435
- K. Svabik et al., "Ultrasound appearances after mesh implantation – evidence of mesh contraction or folding?" Int. Urogynecol J. (2011) 22:529-533
- A. Rogowski et al., "Mesh retraction correlates with vaginal pain and overatice bladder symptoms after anterior vaginal mesh repair" Int. Urogynecol. J. (2013) 24:2087-2092

Methodology

My general opinions are based upon my clinical experience and review of medical and scientific literature and well as my medical education, knowledge, training, practice, and clinical experience.

My case specific opinions are based upon a differential diagnosis methodology. In determining the specific cause of an injury in the medical context it is necessary to "rule in" potential causes of the injury, and then by process of elimination, to "rule out" the least likely causes to arrive at the most likely cause.

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General Opinion No. 1

Facilitating informed consent is an integral part of the practice of medicine. I agree with AMA 8.08 on informed consent. The patient's right of self-decision is particularly important when surgical intervention regarding a permanent medical device is being considered by the patient.

Before a surgeon can inform a patient on the risks/benefits/alternatives to any procedure, including the TVT, the surgeon must be informed on the risks/benefits/alternatives. I have read and relied on Instructions for Use (IFU) for medical devices when informing myself on the risks/benefits/alternatives to a given procedures – including mid-urethral slings. I incorporate the risks and complications referenced in the IFU into my risk-benefit conversation with the patient. I expect the risk and complication information as presented in the IFU to be accurate.

It is my opinion the IFU for the TVT-Secur in 2010 was not sufficient to enable informed consent from the patient. The TVT IFU provided:

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE mesh is designed to minimize the risk of contamination.
- Over correction (i.e. too much tension) applied to the tape may cause temporary or permanent lower urinary tract obstruction.

The words "transitory" and "transient" carry a specific medical meaning. Mosby's medical dictionary defines transient as "pertaining to a condition that is temporary." Using the word transient to describe the human body's foreign body response to the TVT mesh implies the response dissipates with time. In my experience, this does not accurately describe the human body's foreign body response to transvaginal placed mesh.

In my experience when dealing with synthetic mesh-induced foreign body response, the degree of inflammation and scarring around the mesh is intense and

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chronic. More often than not, when removing exposed mesh, I am unable to completely remove the entire mesh implant because of the intensity of inflammation and extensive scarring induced by mesh incorporation into the host tissues. Moreover, in all of my experiences removing mesh, residual scarring of the vagina, peri-vaginal, and those tissues adjacent to the mesh persists and is even more severe in the instances where residual pelvic mesh is left in the patient.

The TVT IFU does not mention: mesh contraction; dyspareunia; mesh shrinkage; scar plate formation; or the difficulty in removing mesh in the event of an adverse event. These events are all part of my informed consent conversation today. I have treated patients implanted with mid-urethral slings, including the TVT for these conditions. It is my opinion that a patient considering a mid-urethral sling cannot be properly consented without discussing these potential adverse events.

General Opinion No. 2

Safer alternatives designs and procedures existed in 2010 that have a lesser risk of erosion and dyspareunia with substantially equivalent efficacy, including autologous fascial slings using rectus fascia sutured to the bladder neck and tied to itself over the rectus fascia. Mrs. Lindberg was unable to receive proper informed consent relating to this safer alternative because of the lack of information in the TVT-Secur IFU inherent to the risks of using synthetic mesh as an alternative to autologous fascia. As such, Dr. Boyd was unable to warn Mrs. Lindberg of the subsequent complications she has suffered from.

Konstantin Walmsley, MD

5/5/2016